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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 02/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/056,991

Applicant(s)

PERRY ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 05 November 2003.
- 2a)  This action is FINAL.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 17-31 is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-16 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on 25 January 2002 is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some \* c)  None of:
    - 1.  Certified copies of the priority documents have been received.
    - 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    - 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a)  The translation of the foreign language provisional application has been received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other:

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of group I, claims 1-16, in the response dated 05 Nov. 2003 is acknowledged.
2. Claims 17-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response dated 05 Nov. 2003.

### *Information Disclosure Statement*

3. The information disclosure statement filed 30 Jan. 2003 has been considered and made of record.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, "said after load device" lacks antecedent basis. It is suggested that the language be changed to --said resistance means--.

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In claim 15, "the semilunar valve" lacks antecedent basis. Note claim 1 refers to "a tissue-engineered construct" not "a semilunar valve".

In claim 16, "said container" lacks antecedent basis. Note claim 16 depends from claim 14 not claim 15. It is suggested that the claim be amended to depend from claim 15.

*Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4-6, 8-10 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ngnyen et al.(US 5,272,909).

With respect to claim 1, the reference of Ngnyen et al. discloses an apparatus comprising:

(a) a base (10) capable of supporting a tissue-engineered construct, the base including a housing (122) having an inlet port (12) and an outlet port (14); (b) a main fluid circuit (44,60,104,28,20) for allowing flow of a fluid media through the housing (122), the main fluid circuit having an efferent section in fluid communication with the outlet port and an afferent section in fluid communication with the inlet port; (c) pressure means (16) in fluid communication with the main fluid circuit for generating physiologic flow of the fluid media through the main fluid circuit, (d) resistance means (58) in fluid communication with the main fluid circuit for replicating an afterload characteristic, the resistance means positioned distal to a tissue-engineered construct on

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the efferent section of the main circuit; and (e) control means (See column 11, lines 23-33, and column 12, lines 26-29) in electronic communication with said pressure means for adjustably controlling the pressure of the fluid media in the main fluid circuit at a level which replicates intraluminal flow, wherein said intraluminal flow of the fluid through said main fluid circuit hemodynamically conditions a tissue-engineered construct prior to in vivo implantation in a ventricular outflow tract.

With respect to claim 4, the pressure means (16) is a pump.

With respect to claim 5, the pump (16) is upstream of the housing (10).

With respect to claim 6, the pump includes check valve (278) (See Figure 3).

With respect to claim 8, the pump includes bellows (298) (See Figure 3).

With respect to claim 9, the housing (10) is hermetically sealed (See Figure 4).

With respect to claim 10, the housing (10) is of a transparent material (See column 7, lines 56-62, and column 9, lines 36-41).

With respect to claim 14, the resistance means (58) is capable of replicating aortic pressure (See column 13, line 26, to column 14, line 34).

3. Claims 1, 4-7, 9-12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (Clin. Phys. Physiol).

With respect to claim 1, the reference of Fischer et al. (See Figure 2 and pages 64-66) discloses an apparatus comprising: (a) a base capable of supporting a tissue-engineered construct, the base including a housing having an inlet port and an outlet port; (b) a main fluid circuit for allowing flow of a fluid media through the housing, the main fluid circuit having an

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efferent section in fluid communication with the outlet port and an afferent section in fluid communication with the inlet port; (c) pressure means in fluid communication with the main fluid circuit for generating physiologic flow of the fluid media through the main fluid circuit, (d) resistance means in fluid communication with the main fluid circuit for replicating an afterload characteristic, the resistance means positioned distal to a tissue-engineered construct on the efferent section of the main circuit; and (e) control means (See page 66) in electronic communication with said pressure means for adjustably controlling the pressure of the fluid media in the main fluid circuit at a level which replicates intraluminal flow, wherein said intraluminal flow of the fluid through said main fluid circuit hemodynamically conditions a tissue-engineered construct prior to in vivo implantation in a ventricular outflow tract.

With respect to claims 4-7, the pressure means is a piston pump with a check valve and positioned upstream of the housing.

With respect to claim 9, the housing is hermetically sealed (See Figure 2).

With respect to claims and 11, the housing is made of acrylic (See page 65).

With respect to claim 12, the controller includes a computer (See page 66).

With respect to claim 14, the resistance means is capable of replicating aortic pressure (See page 67).

#### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ngnyen et al.(US 5,272,909) in view of Thorne et al.(US 3,738,914).

The reference of Ngnyen et al. has been discussed above.

Claim 11 differs by reciting that the transparent material of the housing is acrylic plastic.

The reference of Thorne et al. discloses that it is known in the art to construct an organ or tissue holding chamber of acrylic plastic for visual observation of the perfused member (See column 2, lines 54-56).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ acrylic plastic rather than polycarbonate for the known and expected result of providing an alternative material recognized in the art for forming a holding chamber that is transparent.

Claim 13 differs by reciting that the resistance means includes a compliant tubing having elastic recoil.

The reference of Thorne et al. discloses that it is known in the art to employ an afterload device (44) that includes a tubular silicone bladder (See column 2, lines 30-46).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the afterload device of the Thorne et al. reference in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for creating and/or adjusting the pressure within the fluid circuit as required of the primary reference of Ngnyen et al.

8. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (Clin. Phys. Physiol) in view of Tindale et al. (Clin. Phys. Physiol).

The reference of Fischer et al. has been discussed above.

The above claims differ by reciting that the main fluid circuit includes an auxiliary fluid circuit with a check valve.

The reference of Tindale et al. discloses (See Figure 2) that it is known in the art to provide a valve perfusion system with an auxiliary circuit that returns fluid to a reservoir tank.



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In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the system of the primary reference with an auxiliary circuit for the known and expected result of allowing regurgitant flow of fluid from the main fluid circuit.

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (Clin. Phys. Physiol) in view of Thorne et al. (US 3,738,914).

The reference of Fischer et al. has been discussed above.

Claim 13 differs by reciting that the resistance means includes a compliant tubing having elastic recoil.

The reference of Thorne et al. discloses that it is known in the art to employ an afterload device (44) that includes a tubular silicone bladder (See column 2, lines 30-46).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the afterload device of the Thorne et al. reference in the system of the primary reference for the known and expected result of providing an alternative means recognized in the art for creating and/or adjusting the pressure within the fluid circuit as required of the primary reference of Fischer et al.

***Allowable Subject Matter***

10. Claims 15 and 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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11. The following is a statement of reasons for the indication of allowable subject matter:  
The above claims would be allowable because the prior art of record fails to teach or fairly suggest providing a compressible container in fluid communication with the construct holding housing for allowing radial movement of a semilunar valve during flow of the media through the main fluid circuit.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB